Complete Summary

GUIDELINE TITLE

Recommendations for management of diabetes in Vermont.

BIBLIOGRAPHIC SOURCE(S)

Vermont Program for Quality Health Care, Vermont Department of Health. Recommendations for management of diabetes in Vermont. 4th ed. Montpelier (VT): Vermont Department of Health (VDH); 2004 May. Various p. [107 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On January 5, 2006, GlaxoSmithKline and the U.S. Food and Drug Administration (FDA) notified healthcare professionals about post-marketing reports of new onset and worsening diabetic macular edema for patients receiving rosiglitazone. In the majority of these cases, the patients also reported concurrent peripheral edema. In some cases, the macular edema resolved or improved following discontinuation of therapy and in one case, macular edema resolved after dose reduction. See the FDA Web site for more information regarding rosiglitazone.

COMPLETE SUMMARY CONTENT

IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Gestational diabetes
- Complications of diabetes, including diabetic retinopathy, foot ulcers and infections, microvascular and macrovascular complications, diabetic nephropathy, dyslipidemia, and psychological comorbidities

GUIDELINE CATEGORY

Evaluation
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nephrology
Nursing
Nutrition
Obstetrics and Gynecology
Ophthalmology
Pediatrics
Podiatry
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Physician Assistants
Physicians
Podiatrists
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

- To provide evidence-based recommendations for the management of patients with diabetes
- Specifically to prevent or delay the onset of diabetes and its long-term complications in all patients, and improve pregnancy outcomes for women with gestational diabetes

TARGET POPULATION

- Adults, children, and adolescents with type 1 and type 2 diabetes mellitus and pregnant women with gestational diabetes or pre-existing type 1 or type 2 diabetes
- Individuals at risk for development of type 2 diabetes (screening and prevention)

INTERVENTIONS AND PRACTICES CONSIDERED

Screening and Assessment

1. Assessment of major risk factors for diabetes
2. Counseling of people at high risk for the development of diabetes
3. Monitoring of people with pre-diabetes for the development of diabetes
4. Screening for type 2 diabetes mellitus and gestational diabetes mellitus (GDM)
    - Fasting plasma glucose test (FPG)
    - Oral glucose tolerance test

Treatment/Management

1. Hemoglobin A1C assay
2. Complete dilated and comprehensive eye examination
3. Foot care
    - Annual comprehensive foot exam and risk stratification
    - Peripheral vascular examination (in patients with signs or symptoms of vascular compromise)
    - Management of diabetic foot ulcers and infections
4. Assessment and control of blood pressure (angiotensin converting enzyme [ACE] inhibitors, angiotensin II receptor blockers)
5. Renal management
    - Screening for renal disease
    - Treatment of diabetic nephropathy
6. Lipid management
    - Fasting lipid profile
    - Statin, fibrate, and niacin therapy
    - Nutritional therapy
7. Aspirin therapy (in patients with cardiovascular risk)
8. Self-monitored blood glucose testing (SMBG)
    - Frequency and accuracy
    - Continuous blood glucose monitoring
9. Self-management education
    - Comprehensive educational assessment
    - Comprehensive self-management training and education programs
    - Intensive management education

10. Psychosocial issues
    - Assessment of psychiatric comorbidity
    - Appropriate behavioral strategies to enhance diabetes management

Lifestyle Modification

1. Medical Nutrition Therapy
    - Consultation with a dietitian
    - Development of an individualized nutrition prescription
2. Tobacco use counseling and treatment
    - Screening (at time of initial diabetes diagnosis)
    - Treatment for patients attempting to quit tobacco (nicotine gum, patch, inhaler, nasal spray, lozenge, bupropion [Zyban])
3. Exercise
    - Development of an exercise program
4. Obesity treatment and management (for type 2 diabetes)
    - Weight loss and weight maintenance therapy
    - Increased physical activity
    - Behavior therapy
5. Immunization
    - Influenza vaccination
    - Pneumococcal vaccination

Intensive Insulin Management

1. Continuous subcutaneous insulin infusion (CSII)
2. Multiple daily injections (MDI)

Monitoring and Treatment of GDM

1. Diet, exercise, insulin
2. Postpartum evaluation and education

Pharmacological Agents

Oral Agents

1. Biguanides
    - Metformin (Glucophage, Glucophage XR, Metformin ER)
2. Thiazolidinediones (glitazones)
    - Rosiglitazone (Avandia)
    - Pioglitazone (Actos)
3. Alpha-glucosidase inhibitors
    - Acarbose (Precose)
    - Miglitol (Glyset)
4. Mixtures
    - Avandamet (Avandia and Metformin)
    - Metaglip (Metformin and Glipizide)
    - Glucovance (Glyburide and Metformin)
5. Sulfonylureas
    - Glyburide (Diabeta, Micronase, Glynase)

- Glipizide (Glucotrol, Glucotrol XL)
- Glimepiride (Amaryl)

6. Meglitinides
    - Repaglinide (Prandin)
    - Nateglinide (Starlix)

Insulin

1. Rapid-acting analogs
    - Aspart (Novolog)
    - Lispro (Humalog)
2. Short acting
    - Human Regular
3. Intermediate Acting
    - Human NPH
    - Human Lente
4. Long Acting
    - Human UltraLente
5. Basal
    - Glargine (Lantus)
6. Pre-Mixed
    - Humalog Mix 75/25 NPL/Lispro
7. Human
    - Human 70/30 NPH/R or 70 aspart protamine suspension/ 30 aspart (depending on the brand)
    - Human 50/50 NPH/R

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality
- Rates of diabetes-related complications (i.e., microvascular events; cardiovascular events; renal failure; psychological, metabolic, and pregnancy outcomes)
- Prevalence and incidence of diabetes and diabetes-related complications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

A summary of recommendations is provided below. For the full recommendations see original guideline document.

Hemoglobin A1C (A1C)

- The American Diabetes Association (ADA) suggests a target A1C <7 percent.
- The ADA recommends re-evaluation of the management plan for anyone unable to achieve desired goals.
- Measure A1C every three to six months.

Ophthalmic Exams

- Type 1 diabetes

  Schedule yearly complete dilated and comprehensive eye examinations starting 3 to 5 years after diagnosis and/or at 10 years of age, whichever is later.

- Type 2 diabetes

  Schedule yearly complete dilated and comprehensive eye examinations starting shortly after diagnosis.

- Pregnant women with pre-existing type 1 or type 2 diabetes

  Schedule a first trimester examination with close follow-up during pregnancy and for one year postpartum.

- Women with type 1 or type 2 diabetes who are planning pregnancies

  Schedule a complete dilated and comprehensive eye examination pre-conception, with counseling on the risk of development and/or progression of diabetic retinopathy.

- Cataracts and glaucoma are more common in people with diabetes.

Foot Exams, Ulcers, and Infections

- Perform an annual comprehensive foot exam.
- Identify patients with high-risk feet.
- Closely monitor high-risk feet.
- Consider peripheral vascular studies in patients with signs or symptoms of vascular compromise.
- Ulcers should respond to treatment within a month.
- Treat foot infections aggressively.

Blood Pressure Measurement

- Measure blood pressure at every visit.
- The goal for blood pressure is less than 130/80 mmHg.

Renal Disease

- Screen urine for evidence of renal disease every year in both type 1 and type 2 diabetes.
- For patients with nephropathy, the major goals are to maintain blood pressure (BP) <130/80 mmHg and to minimize proteinuria or albuminuria.

Lipid Management for Adults

- The primary treatment goal is a low-density lipoprotein (LDL) <100 mg/dL both for people with known macrovascular disease and those without macrovascular disease.
- Obtain a fasting lipid profile annually for both type 1 and type 2 diabetes, more frequently if needed to achieve goals.
- If lipid values are low risk (LDL <100 mg/dL, high-density lipoprotein [HDL] >50 mg/dL, and triglycerides <150 mg/dL) repeat lipid profile every two years depending on cardiovascular disease (CVD) status.
- Consider statin therapy for all patients with diabetes over age 40 and a total cholesterol >135 mg/dL, based on evidence from the Heart Protection Study.

Self-Management Education

- Diabetes self-management education involves a continuum of services ranging from the teaching of Survival Skills to Comprehensive Self-Management Education Programs to Intensive Management.
- Educational needs should be assessed at time of diagnosis and whenever there is poor clinical control or a major change in therapy.
- Licensed health care professionals with specific training in diabetes and training in education of people with diabetes should teach self-management education.
- Self-management education needs and plans should be documented in the medical record and acknowledged by all providers.

Medical Nutrition Therapy

- Medical Nutrition Therapy is an integral component of diabetes management and of diabetes self-management education.
- A registered dietitian (RD), certified in Vermont (CD) who is knowledgeable and skilled in implementing diabetes medical nutrition therapy should be the team member with primary responsibility for nutrition care and education.

Self-Monitored Blood Glucose Testing (SMBG)

- SMBG is an important tool for achieving glycemic control.
- The frequency of SMBG should be individualized based on type of diabetes, glucose goals, and other factors.

Tobacco Use Status and Counseling

- Screen at time of initial diabetes diagnosis.
- Ask tobacco users about status of tobacco use at each visit.
- Advise every tobacco user to quit.

- Assist every tobacco user who is willing to make a quit attempt to access treatment.
- Follow up with every tobacco user at every visit.

Diabetes Mellitus And Exercise

- Exercise is an important therapeutic tool for people with diabetes.
- Exercise programs should be individualized to maximize benefit and minimize risk.

Obesity Treatment And Management For Type 2 Diabetes

- Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes.
- Weight loss and weight maintenance therapy should employ the combination of low-calorie diets, increased physical activity, and behavior therapy.

Immunization

- Annual influenza vaccine is recommended for all patients with diabetes.
- Pneumococcal vaccine is recommended for all patients with diabetes.

Screening For Type 2 Diabetes Mellitus

- Individuals who are at high-risk for type 2 diabetes should be screened for disease.
- A fasting plasma glucose test (FPG) is the simplest and least expensive screening test.
- A FPG result $\geq$126 mg/dL on two separate occasions is diagnostic of diabetes; values of 100 to 125 mg/dL are termed impaired fasting glucose, and values <100 mg/dL are considered normal.
- Individuals with impaired glucose tolerance can significantly reduce the risk of developing type 2 diabetes through intervention with diet and exercise.

Gestational Diabetes Mellitus (GDM)

- Prenatal screening for GDM is important; however, there is controversy about whether screening should be universal or selective.
- Women with GDM are at extremely high risk for developing type 2 diabetes later in life and should be monitored closely.

Medications

- Medication Therapy can involve oral agents, insulin, or a combination of these two therapies.
- Medication Therapy is a therapeutic tool for use in lowering and maintaining blood glucose levels.

Intensive Insulin Management

- Candidates for Intensive Insulin Management must be motivated to improve glucose control and able to assume responsibility for their day-to-day care.
- Use of Intensive Insulin Management should be initiated, monitored, and supported by a Comprehensive Diabetes Team.
- Intensive Insulin Management is essential during pregnancy and recommended for all who wish to reduce their risk of diabetes complications.

Psychosocial Issues in Diabetes Care

- Assess key psychosocial factors affecting chronic care.
- Choose appropriate behavioral strategies to enhance diabetes management.

Primary Prevention

- Counsel people at high risk for the development of diabetes on the benefits of moderate weight loss and exercise (weight loss of 5 to 7% with 150 minutes of exercise per week).
- Screen people at high risk.
- Monitor people with pre-diabetes for the development of diabetes every 1 to 2 years.
- Based on current knowledge, the ADA does not support the routine use of drug therapy in the prevention of Type 2 diabetes.

CLINICAL ALGORITHM(S)

Clinical algorithms are provided in the original guideline document for:

- Foot Ulcer in Diabetic Patient
- Foot Infection in Patient with Diabetes
- Screening for Renal Disease
- Screen for Tobacco Use

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. Recommendations are based on a combination of clinical experience and research-based evidence.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Decrease in morbidity and mortality rates associated with diabetes
- Glycemic control markedly reduces the progression of microvascular complications.
- Decreased rate of progression to type 2 diabetes
- Improvements in outcome for pregnant women with gestational diabetes

POTENTIAL HARMS

- Insulin may cause hypoglycemia.
- Side effects of intensive therapy may include severe hypoglycemic reactions and weight gain.
- The decision to administer the influenza vaccine for a patient with a history of Guillain-Barre Syndrome (GBS), especially if it occurred within six weeks of influenza vaccination, needs to be individualized in consultation with a vaccine expert.
- Side effects of oral agents (see section 16 of the original guideline document for side effects of specific medications).

CONTRAINDICATIONS

CONTRAINDICATIONS

- Bupropion SR (Zyban) is contraindicated in patients with seizures, head trauma, anorexia, and alcohol abuse.
- Significant peripheral neuropathy is a contraindication to weight bearing exercise.
- Known anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine contraindicates vaccination, unless there is a high risk of complications from influenza infection and appropriate allergy evaluation and desensitization has occurred. Moderate to severe acute illness is also a contraindication until symptoms have abated.
- Moderate or severe acute illness is a contraindication to a first dose of pneumococcal vaccine. A severe allergic reaction to the pneumococcal vaccine is a contraindication to revaccination.
- In pediatric patients, live, attenuated, intranasal vaccine is contraindicated for those with certain medical conditions, including diabetes.
- Metformin (Glucophage, Glucophage XR, Metformin ER) is contraindicated in men with serum creatinine 1.5 or in females with 1.4 or greater, in patients with hepatic dysfunction, in acute or chronic lactic acidosis and may be contraindicated in patients with chronic heart failure.
- Glyburide (Diabeta, Micronase, Glynase) is contraindicated in patients with diabetic ketoacidosis, severe infection, surgery, or trauma.
- Repaglinide (Prandin) contraindicated in patients with diabetic ketoacidosis, severe infection, surgery, or trauma.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The guideline developers encourage providers to modify these recommendations to meet the unique needs of each person with diabetes. These recommendations will be appropriate for treatment of most adults with diabetes most of the time, and the need for major modifications should not be common.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Vermont Program for Quality Health Care, Vermont Department of Health. Recommendations for management of diabetes in Vermont. 4th ed. Montpelier (VT): Vermont Department of Health (VDH); 2004 May. Various p. [107 references]

ADAPTATION

The guideline was adapted from American Diabetes Association: Clinical Practice Recommendations 2004. Diabetes Care. 2004 Jan; 27 Suppl 1.

DATE RELEASED

2004 May

GUIDELINE DEVELOPER(S)

Vermont Program for Quality in Health Care - Private Nonprofit Organization

SOURCE(S) OF FUNDING

Vermont Program for Quality in Health Care and the Vermont Department of Health

GUIDELINE COMMITTEE

Diabetes Steering Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

Blue Cross and Blue Shield of Vermont - Managed Care Organization
Cigna HealthCare - Managed Care Organization
MVP Health Care - Managed Care Organization
Office of Vermont Health Access - State/Local Government Agency [U.S.]

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Vermont Program for Quality in Health Care Web site.

Print copies: Available from the Vermont Program for Quality in Health Care, 132 Main Street, P.O. Box 1356, Montpelier, Vermont 05601; Phone: (802) 229-2152; Fax: (802) 229-5098; E-mail: mail@vpqhc.org

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Learning to Live Well with Diabetes. An on-line resource for patients with diabetes developed by the Vermont Department of Health.

Electronic copies: Available from the Vermont Department of Health Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on April 6, 2005. The information was verified by the guideline developer on May 3, 2005. This summary was updated by ECRI on January 11, 2006 following the U.S. Food and Drug Administration advisory on rosiglitazone.

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Date Modified: 9/18/2006